



DEPARTMENT OF VETERANS AFFAIRS

8320-1

38 CFR Part 3

RIN 2900-AO32

Disease Associated With Exposure to Certain Herbicide Agents: Peripheral Neuropathy

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to amend its adjudication regulation concerning presumptive service connection for acute and sub-acute peripheral neuropathy associated with exposure to certain herbicide agents. This proposed amendment is necessary to implement a decision by the Secretary of Veterans Affairs to clarify and expand the terminology regarding presumption of service connection for peripheral neuropathy associated with exposure to certain herbicide agents.

DATES: Comments must be received by VA on or before [Insert date 60 days after date of publication in the FEDERAL REGISTER].

ADDRESSES: Written comments may be submitted through <http://www.regulations.gov>; by mail or hand-delivery to Director, Regulations Management (02REG), Department of Veterans Affairs, 810 Vermont Ave., NW, Room 1068, Washington, DC 20420; or by fax to (202) 273-9026. (This is not a toll free number). Comments should indicate that they are submitted in response to "RIN 2900-

AO32 - Disease Associated With Exposure to Certain Herbicide Agents: Peripheral Neuropathy." Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461-4902 for an appointment. (This is not a toll free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Dr. Nick Olmos-Lau, Medical Officer, Regulations Staff (211D), Compensation Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420, (202) 461-9695. (This is not a toll free number.)

SUPPLEMENTARY INFORMATION: As required by the Agent Orange Act of 1991, codified in part at 38 U.S.C. 1116, the Department of Veterans Affairs (VA) asks the National Academy of Sciences (NAS) to evaluate scientific literature regarding possible associations between the occurrence of a disease in humans and exposure to an herbicide agent. Congress mandated that NAS to the extent possible determine (1) Whether there is a statistical association between exposure to herbicide agents and the illness, taking into account the strength of the scientific evidence and the appropriateness of the scientific methodology used to detect the association; (2) the increased risk of illness among individuals exposed to herbicide agents during service in the Republic of Vietnam during the Vietnam era; and (3) whether a plausible biological

mechanism or other evidence of a causal relationship exists between exposure to the herbicides and the illness. That statute provides that whenever the Secretary determines, based on sound medical and scientific evidence, that a positive association (i.e., the credible evidence for the association is equal to or outweighs the credible evidence against the association) exists between an illness and exposure to herbicide agents in an herbicide used in support of U.S. military operations in the Republic of Vietnam, the Secretary will publish regulations establishing presumptive service connection for that illness.

On September 29, 2011, NAS publicly released the report titled, Veterans and Agent Orange: Update 2010, which describes the law mandating the NAS review and highlights of the ninth biennial update. In Update 2010, NAS conducted a comprehensive search of all medical and scientific studies on health effects of herbicides used in the Vietnam War, including more than 6,600 potentially relevant studies, of which 1,300 were carefully reviewed, and about 65 ultimately contributed new information. Relevant animal studies, as with previous biennial "Agent Orange Updates," were also reviewed to determine biological plausibility and possible mechanisms of action.

Compared to previous reports, a notable change is the NAS decision to revise and clarify the description of the types of peripheral neuropathy that may be associated with exposure to an herbicide agent to include all early-onset peripheral neuropathies, regardless of whether they are transient or persistent in nature. In 1996, NAS found

that there was “limited/suggestive evidence” of an association between herbicide exposure and the occurrence of “acute and subacute transient peripheral neuropathy.” In subsequent updates, NAS continued to find “limited or suggestive evidence” of an association between herbicide exposure and that condition, but in 2004, NAS revised its description of the condition to “early onset transient peripheral neuropathy.” This terminology reflected NAS’s judgment that peripheral neuropathy associated with herbicide exposure would have its onset proximate in time to herbicide exposure and would be of a transient nature that would resolve over time. Pursuant to the 1996 NAS Report, VA established a regulatory presumption of service connection for “acute and subacute peripheral neuropathy,” which is defined as “transient peripheral neuropathy that appears within weeks or months of exposure to an herbicide agent and resolves within two years of the date of onset.”

In Update 2010, NAS concluded that there is “limited or suggestive evidence of an association” between exposure to the chemicals of interest and “early-onset peripheral neuropathy that may be persistent.” This description reflects NAS’ decision to remove the term “transient” from the description of the peripheral neuropathies associated with herbicide exposure. In Update 2010, NAS reexamined several studies reviewed in prior NAS reports concerning early-onset peripheral neuropathy in individuals exposed to herbicides and found that, in several of the studies, some exposed individuals continued to exhibit neurological symptoms several years after exposure. NAS explained that, for the purpose of identifying peripheral neuropathies related to herbicide exposure, the diagnosis of the condition is contingent upon the

proximity of the disease onset to the exposure, rather than upon the adverse outcome having a transitory nature. NAS stated that, in cases of an immediate response of peripheral neuropathy following a toxic exposure, stabilization or improvement is the rule after exposure ends, but that the recovery may not be complete and the degree of recovery can depend on the severity of the initial impairment and the particular exposure. NAS further noted that there may be persistent subclinical effects that are not immediately apparent but that may be detected by detailed examination and testing. Accordingly, NAS concluded that early-onset peripheral neuropathy associated with herbicide exposure is not necessarily a transient condition. However, NAS reaffirmed the conclusion in each of its prior reports that no data suggests that exposure to the chemicals of interest can lead to the development of delayed-onset chronic neuropathy many years after termination of exposure in those who did not originally experience early-onset neuropathy.

As stated above, VA's current regulation presumes service connection for "acute and subacute peripheral neuropathy" which the regulation defines as "transient peripheral neuropathy that appears within weeks or months of exposure to an herbicide agent and resolves within two years of the date of onset." After careful review of NAS' conclusions, VA proposes to replace the terms "acute and subacute" in 38 CFR 3.309(e) with the term "early-onset" and remove the Note to the regulation requiring that the neuropathy be "transient." Accordingly, VA proposes to remove the current requirement that acute and subacute peripheral neuropathy appear "within weeks or

months" after exposure and remove the requirement that the condition resolve within two years of the date of onset in order for the presumption to apply.

For purposes of consistency, VA further proposes to replace the terms "acute and subacute" with "early-onset" in 38 CFR 3.307(a)(6)(ii) requiring peripheral neuropathy to become manifest to a degree of 10 percent or more within one year after the last date of herbicide exposure in order to be subject to presumptive service connection under 38 CFR 3.309(e).

This amendment would clarify that presumptive service connection for early-onset peripheral neuropathy will not be denied solely because the peripheral neuropathy persisted for more than two years after the date of last herbicide exposure. However, this amendment would not change the current requirement that peripheral neuropathy must have become manifest to a degree of 10 percent or more within one year after the date of last exposure in order to qualify for the presumption of service connection. In Update 2010, the NAS found that evidence did not indicate an association between herbicide exposure and delayed-onset peripheral neuropathy, which NAS defined as peripheral neuropathy having its onset more than one year after exposure.

The one-year presumption period in 38 CFR 3.307(a)(6)(ii) is measured from the date of last herbicide exposure in service. In many cases, such as those based on service in the Republic of Vietnam during the Vietnam era, this would require evidence

that peripheral neuropathy was manifest to a degree of ten percent or more during a period several years or decades in the past. Under 38 U.S.C. § 1110, VA may pay disability compensation for disability resulting from a service-connected disease or injury. In adjudicating individual claims for benefits, it may therefore be necessary to determine whether evidence shows that current disability exists as a result of the service-connected peripheral neuropathy that was manifest within the presumption period. VA will develop and decide these issues on a case-by-case basis in accordance with established law.

Additionally, we propose to revise 38 CFR 3.816(b)(2), the regulation governing retroactive awards for certain diseases associated with herbicide exposure as required by court orders in the class action litigation in the case of Nehmer v. U.S. Department of Veterans Affairs. Currently § 3.816(b)(2) states that the Nehmer court orders apply to presumptions established before October 1, 2002, and lists the diseases covered by those presumptions, including “acute and subacute peripheral neuropathy.” Rather than revising this list, we propose to remove the list of conditions and the October 1, 2002, date and insert language clarifying that the Nehmer court orders apply to the presumptions listed in § 3.309(e). This change is necessary because the district court and the U.S. Court of Appeals for the Ninth Circuit in Nehmer found the date restriction and the corresponding listing of presumptive conditions based on herbicide exposure found at § 3.816(b)(2) to be invalid as it is not inclusive of all conditions the Secretary has determined to be presumptively service connected based on herbicide exposure under the Agent Orange Act of 1991. Therefore, VA proposes to remove paragraphs

(b)(2)(i)-(ix) and the phrase “before October 1, 2002” and to add a reference to § 3.309(e) that reflects the inclusive listing in the introduction to paragraph (b)(2).

Paperwork Reduction Act

This document contains no provisions constituting a collection of information under the Paperwork Reduction Act (44 U.S.C. 3501-3521).

Regulatory Flexibility Act

The Secretary hereby certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601-612. This proposed rule would not affect any small entities. Only VA beneficiaries could be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), this proposed rule is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory

Planning and Review) defines a “significant regulatory action,” which requires review by the Office of Management and Budget (OMB), as “any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this Executive Order.”

The economic, interagency, budgetary, legal, and policy implications of this proposed rule have been examined, and it has been determined to be a significant regulatory action under Executive Order 12866 because it raises novel legal or policy issues.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for

inflation) in any year. This proposed rule would have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance Numbers and Titles

The Catalog of Federal Domestic Assistance program numbers and titles for this rule are 64.109, Veterans Compensation for Service-Connected Disability; and 64.110, Veterans Dependency and Indemnity Compensation for Service-Connected Death.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. John R. Gingrich, Chief of Staff, Department of Veterans Affairs, approved this document on April 5, 2012, for publication.

List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Disability benefits, Health care, Pensions, Radioactive materials, Veterans, Vietnam.

Dated: August 7, 2012

Robert C. McFetridge,
Director, Regulation Policy and Management,
Office of the General Counsel
Department of Veterans Affairs

For the reasons set out in the preamble, VA proposes to amend 38 CFR part 3 as follows:

PART 3 — ADJUDICATION

Subpart A-Pension, Compensation, and Dependency and Indemnity Compensation

1. The authority citation for part 3, subpart A continues to read as follows:

Authority: 38 U.S.C. 501(a), unless otherwise noted.

2. In § 3.307(a)(6)(ii), remove the term “acute and subacute peripheral neuropathy” and add, in its place, “early-onset peripheral neuropathy”.

3. Amend § 3.309(e) by:

- a. Removing the term “Acute and subacute peripheral neuropathy” and adding, in its place, “Early-onset peripheral neuropathy”.

- b. Removing Note 2.

- c. Redesignating Note 3 as Note 2.

4. Amend § 3.816(b)(2) by:

- a. In the introductory text, removing “before October 1, 2002.”

b. In the introductory text, removing the period after "chloracne" and all that follows through the end of the introductory text and adding, in its place, ", as provided in § 3.309(e)."

c. Removing paragraphs (i) through (ix).

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